

Human Albumin Grifols® 5%

SOLUTION FOR INJECTION

Composition

Each ml contains:

- Active ingredient:

Human albumin	0.050 g
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- Excipients:
Sodium caprylate, sodium N-acetyltryptophanate and water for injection.

Solution with 50 g plasmaprotein/l with a human albumin content of at least 95%.
The solution contains between 130 - 160 mmol/l of sodium and not more than 2 mmol/l of potassium.

Pharmaceutical form and content

Injectable solution with 5 g/100 ml of human albumin.

Activity

Human Albumin Grifols® 5% is a sterile serum albumin solution derived from pooled venous blood plasma and obtained by fractionation according to Cohn's method with cold ethanol.

Each unit of plasma used in the preparation of Human Albumin Grifols® 5% has been found non-reactive for the hepatitis B surface antigen (HBsAg), for the antibodies to human immunodeficiency viruses (HIV-1 and HIV-2) and to the hepatitis C virus (HCV).

The product is pasteurised at 60 °C for 10 hours.

Holder of the marketing authorisation

Instituto Grifols, S.A.

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Therapeutic indications

Human Albumin Grifols® 5% is indicated for:

- Albumin replacement in patients with albumin and blood volume deficiency.

Suitable for premature born babies and dialysis patients.

Contraindications

- A history of allergic reaction to albumin preparations.
- Allergic reaction to this preparation.
- All conditions in which hypervolaemia and its consequences (e.g. increased stroke volume, elevated blood pressure) or haemodilution could represent a special risk for the patient.

Examples of such conditions are:

- Decompensated cardiac insufficiency
- Hypertension
- Oesophageal varices
- Pulmonary edema
- Haemorrhagic diathesis
- Renal and post-renal anuria
- Severe anaemia

Precautions

Human Albumin Grifols® 5% is for intravenous administration use.

If allergic reactions occur, the infusion should be stopped immediately. If allergic reactions persist then appropriate treatment is recommended. In anaphylactic reactions, treatment should follow the current recommendations for shock therapy.

If comparatively large volumes are to be replaced, controls of coagulation and haematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes). If the haematocrit drops below 30%, packed red cells should be given to maintain the oxygen transport capacity of the blood.

When medicinal products prepared from human blood or plasma are administered, infectious diseases due to the transmission of infective agents cannot be totally excluded. This applies also to pathogens of hitherto unknown nature.

To reduce the risk of transmission of infective agents selection of donors and donations by suitable measures is performed and removal and/or inactivation procedures are included in the production process.

Interactions

No interactions of human albumin with other products are known so far.

Incompatibilities

Human albumin should not be mixed with other drugs, whole blood and packed red cells.

Warnings

Pregnancy and lactation

The safety of human albumin for use in human pregnancy has not been established in controlled clinical trials. Experimental animal studies are insufficient to assess the safety with respect to reproduction, development of the embryo or foetus, the course of gestation and peri and postnatal development. However, human albumin is a normal constituent of human blood. Therefore albumin may be used, if clearly needed, during pregnancy and lactation.

Effects on ability to drive

There are no indications that human albumin may impair the abilities to drive or to operate machines.

Posology

In general, the dosage and the infusion-rate should be adjusted to the patient's individual requirements.

When human albumin is used in replacement therapy, the dosage required is guided by the usual circulatory parameters. The lowest limit for the colloidal osmotic pressure is 20 mm Hg (2.7 kPa). If human albumin is to be administered, the dose in grams required can be estimated using the following calculation:

$$[\text{required total protein (g/l)} - \text{actual total protein (g/l)}] \times \text{plasma volume (l)} \times 2$$

The physiological plasma volume may be calculated as approximately 0.04 l/kg body weight.

As the formula in any case is only approximate, laboratory monitoring of achieved protein concentration is recommended.

In cases of extensive substitution and in cases with haematocrit below 30% see "Precautions".

Paediatric use:

In children the physiological plasma volume is age-dependent, this fact must be taken into account.

Instructions for use

Human albumin is ready for use and is for administration by intravenous infusion only. The infusion-rate should be adjusted according to the individual circumstances and the indication, but should normally be set up at 5 ml/min in 5% solutions.

Maximum infusion rates should not exceed 30 ml/min during plasma exchange.

If large volumes are administered the product should be warmed to room or body temperature before use.

Usually the solution is clear or slightly opalescent. Do not use solutions which are cloudy or have deposits.

Once the infusion container has been opened the contents should be used immediately.

Any unused solution must be discarded appropriately even if refrigerated.

Overdose

Hypervolaemia may occur if the dosage and rate of infusion are too high.

At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), or increased blood pressure, raised central venous pressure and pulmonary edema, the infusion is to be stopped immediately. Additionally, diuresis or cardiac output should be increased according to the severity of the clinical situation.

Undesirable effects

Side effects after infusion of human albumin are rare. Mild reactions such as flush, urticaria, fever, nausea normally disappear rapidly when the infusion-rate is slowed or the infusion is stopped.

In single cases reactions reaching as far as shock may occur. In these cases, the infusion should be stopped and an appropriate treatment should be initiated.

When medicinal products prepared from human blood or plasma are administered, infectious diseases due to transmission of infective agents cannot be totally excluded (see item corresponding to Precautions).

If any adverse reaction, not enclosed in this item, appears, inform your physician or pharmacist.

Storage

Human Albumin Grifols® 5% has a shelf-life of 3 years when stored at a temperature between 2 - 25 °C.

Shelf-life

Do not use after the expiry date given on the label.

Sizes

- Human Albumin Grifols® 5%:

Flasks of 100 ml, 250 ml and 500 ml.

Under medical prescription

Keep out of the reach and sight of children